K100385
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510(k) Summary
(per 21 CFR 807.92(c))

1. **Applicant**

Luv n' care®, Ltd.
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Monroe, LA 71201

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MAR 24 2010

Date Prepared: November 11, 2009

2. **Device Name**

Device Name:	Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump
Device:	pump, breast, powered
Regulation Description:	Powered breast pump.
Regulation Number:	884.5160
Product Code:	HGX
Device Class:	II
Review Panel:	Obstetrics/Gynecology

3. **Predicate Devices**

The Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump is substantially equivalent to the following device:

510(k) Number	Device	Applicant
K052047	ISIS iQ UNO Handheld Electronic Breast Pump	Avent America, Inc.

4. **Indications for Use**

The Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump is indicated to express and collect milk from the breasts of lactating women.

5. Description of the Device

The Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump is a BPA-free breast pump designed with an electronic memory that allows the lactating mother to save and control personal pump settings or use one of the two settings that are already pre-programmed. The "soft flex" funnel protects and actuates in and out, replicating baby's suckling action and stimulating a fast, natural let-down. In addition to mains power, this single electronic pump can also operate using battery power or as a manual pump.

6. Summary of the Technical Characteristics

- Performance

  The components of the Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump were evaluated to ensure that the recommended cleaning/sanitization procedures would not significantly alter the material/geometry of the pump components nor negatively impact the overall efficiency/ operation of the pump. In addition, laboratory testing was conducted to estimate the "life cycle" of the device as approximately 1.6 years. Finally, testing was conducted on the Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump and the ISIS iQ UNO Handheld Electronic Breast Pump as to evaluate and compare the general performance characteristics (i.e., suction, speeds, and flow rates) of these devices. Based on this study, both devices performed substantially equivalent in terms of suction, speeds, and flow rate (i.e., rate of fluid/milk extraction).

- Biocompatibility

  The Softflex™ Funnel (or Flex Horn) is the only patient-contacting component associated with the Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump. This component was tested and passed all required biocompatibility testing (i.e., cyctotoxicty, sensitization, and intracutaneous reactivity, and acute systemic toxicity) conducted in accordance with ISO 10993. In addition, the milk-contacting components comply with 21CFR 174 and 177.

- Electrical

  The Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump complies with the medical electrical equipment requirements defined by IEC 60601-1-2 and IEC/UL 60601-1 for electromagnetic compatibility and electrical safety, respectively.

7. Safety and Effectiveness

The Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump is as safe and effective as the predicate device listed in this 510(k) submission. The Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump and the ISIS iQ UNO Handheld Electronic Breast Pump (K052047) have the same indications for use and are similar in both design and function. Any differences in technological characteristics between the Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump and the predicate device do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Luv N' Care, Ltd.
c/o Casey Conry
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

MAR 2 4 2010

Re: K100385
Trade/Device Name: Nuby™ Natural Touch Rhythm™ Dual Action Electric Breast Pump
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 10, 2010
Received: March 11, 2010

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100385

Device Name: Nuby™ Natural Touch Rhythm™ Dual Action Electric Pump Electric Breast Pump

Indications for Use:

The Nuby™ Natural Touch Rhythm™ Dual Action Electric Pump Electric Breast Pump is indicated to express and collect milk from the breasts of lactating women.

Prescription Use (Part 21 CFR 801 Subpart D)		AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	X

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K100385